

Oct 03 04 12:02p

ER Luger TGottlieb

212 448 9373

p. 1

PAGE 1/7 * RCVD AT 10/3/2004 1:19:27 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/0 * DNIS:8729306 * CSID:212 448 9373 * DURATION (mm-ss):02:34

RECEIVED
CENTRAL FAX CENTER

OCT 03 2004

*Missing 6 pages
p. 7 - not completely
printed*

FACSIMILE COVER SHEET

RECEIVED
CENTRAL FAX CENTER

OCT 03 2004

NORRIS MCLAUGHLIN & MARCUS, P.A.

875 Third Avenue
18th Floor
New York, NY 10022
Tel.: (212) 808-0700
Fax.: (212) 808-0844

Date:

OCTOBER 3, 2004

To:

MAIL STOP AMENDMENT
Examiner Jeanne Anne Goldberg
US Patent and Trademark Office
Fax: 703-872-9306

Subject:

USSN: 09/979,513
Our Ref.: 101195-67

From:

Theodore A. Gottlieb

Comments:

Filing of: response to Office Action dated April 2, 2004, including Amendment under 37 CFR 1.111 and Petition for Three Months Extension of Time

If you have any questions or need further information, please contact us.

You should receive #13 pages including this cover sheet.

The information contained in this facsimile message is intended only for the personal and confidential use of the recipient(s) named above. This message may be an attorney-client communication and as such is privileged and confidential. If the reader of this message is not the intended recipient or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error and that any review, dissemination, distribution, or copying of this message is strictly prohibited. If you have received this communication in error, please notify us immediately at the number above and discard the original message.

Atty's Docket: 101195-67

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO. : 09/979513
APPLICANT : Peter DANIEL et al.,
FILED : 25 February 2003
EXAMINER : J. A. Goldberg
ART UNIT : 1634
FOR : METHOD FOR DETECTING THE EFFECT OF DIFFERENT
CHEMO-THERAPEUTIC AGENTS AND/OR RADIATION THERAPY
IN MALIGNANT DISEASES AND METHOD FOR SELECTING
MORE EFFECTIVE THERAPEUTIC AGENTS FOR THE THERAPY
THEREOF

RECEIVED
CENTRAL FAX CENTER

OCT 03 2004

Hon. Commissioner of Patents
PO BOX 1450
Alexandria, VA 22313-1450

September 30, 2004

RESPONSE PURSUANT TO 37 CFR § 1.111

Sir:

This communication is in response to the office action of April 2, 2004.
Entry of the amendments and consideration of the remarks is respectfully requested.

<u>Section</u>	<u>Begins on page</u>
Claims	2
Amendment to spec.	5
Remarks	6
Signature/Certificate	9

Atty's Docket: 101195-67

IN THE CLAIMS

Amend claims as shown below; cancel claims 7-8. Add new claims 11-13.

1 (Currently amended) Method-A method for detecting the effect of different chemotherapeutic agents and/or radiation in malignant diseases by determining the expression levels of the p53 gene and/or variants thereof, comprising the steps,

(a) collecting cells and/or tissue from a subject with a malignant disease,

(b) determining the expression of the p53 gene or variants thereof by analysis of p53-specific RNA, in a portion of the cells and/or tissue,

(c) placing into culture an additional portion of the cells and/or tissue, and treating the cultured cells and/or tissue with one or more cytostatic compounds and/or radiation treatments,

(d) determining the expression profile of the p53 gene or variants thereof, in the cells and/or tissues by analysis of p53-specific RNA, and, assigning an observed change in the treated cells' and /or tissue's expression profile to the corresponding treatment with one or more cytostatic compounds and/or radiation, and

(e) comparing the expression profile obtained in step (b) with an expression profile of step (d) and based on the comparing, selecting one or more cytostatic compounds and/or radiation treatments for administering to the subject,

wherein the expression profiles of apoptosis-regulating and/or cell growth-regulating genes and/or individual differences (mutations) in the gene sequences is determined

Atty's Docket: 101195-67

~~and the changes associated with chemotherapeutic agents and/or radiation therapy are identified, represented and diagnostically evaluated.~~

2. (Currently amended) ~~Method A method~~ in accordance with claim 1, wherein the expression profiles of one or more additional genes are determined, the additional genes being selected from the group consisting of the Bcl-2 family, preferably Bax, p53, p16, caspases, Rb, cyclins, inhibitors of cyclin-dependent kinases (CDKIs), ATM and inhibitors of apoptosis proteins (IAPs), and/or mutations-variants thereof in the genes are determined using protein or DNA/RNA analyses and evaluated singly or in various combinations.

3. (Currently amended) ~~Method A method~~ in accordance with claim 1, wherein individual differences in the sequence of apoptosis and/or cell growth-regulating genes ~~and and/or the their expression profiles of their gene products, which occur in malignant diseases, are related correlated with the apoptosis and/or cell growth-regulating genes' to an individually different responsiveness to drugs cytostatic compounds and/or radiation. and are evaluated, particularly with regard to their relevance to the response to therapy.~~

4. (Currently amended) Method for selecting ~~more efficacious~~ therapeutic agents for the treatment of malignant diseases, wherein the ~~status-expression profiles of one or more cell cycle genes and/or of apoptosis-associated target genes or of their gene products thereof, in body fluids, cells or organs are determined ex vivo and the more efficacious~~